

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) An oral Oral pharmaceutical formulation in the form of a granulate comprising more than 60% by weight of mesalazine or a pharmaceutically acceptable salt thereof.
2. (Currently Amended) The pharmaceutical Pharmaceutical formulation according to claim 1 comprising more than 70% by weight of mesalazine or a pharmaceutically acceptable salt thereof.
3. (Currently Amended) The pharmaceutical Pharmaceutical formulation according to claim 1 comprising more than 80% by weight of mesalazine or a pharmaceutically acceptable salt thereof.
4. (Currently Amended) The pharmaceutical Pharmaceutical formulation according to claim 1, having in vitro release characteristics such that of mesalazine of at least 40% of the total amount of mesalazine or pharmaceutically acceptable salt thereof in the formulation is released after 240 min, of the total amount of mesalazine in the formulation, when measured in a model system using a USP Paddle System 2 operated at 37°C with stirring at 100 rpm.
5. (Currently Amended) The pharmaceutical Pharmaceutical formulation according to claim 1, having in vitro release characteristics of mesalazine of such that
 - a) 5 – 25 % of the total amount of mesalazine or pharmaceutically acceptable salt thereof in the formulation is released after 15 min;
 - b) 30 – 70 %, preferably 40 – 60 %, of the total amount of mesalazine or pharmaceutically acceptable salt thereof in the formulation is released after 90 min; and

c) 75 – 100 % of the total amount of mesalazine or pharmaceutically acceptable salt thereof in the formulation is released after 240 min;
of the total amount of mesalazine in the formulation when measured in a model system using a USP Paddle System 2 operated at 37°C with stirring at 100 rpm.

6. (Currently Amended) The pharmaceutical Pharmaceutical formulation according to claim 1, having a similarity factor f_2 above 30, ~~preferably above 40, more preferred above 50~~, as compared to a standard formulation having the in vitro release characteristics of mesalazine of such that

- a) 12 % of the total amount of mesalazine in the standard formulation is released after 15 min;
- b) 50 % of the total amount of mesalazine in the standard formulation is released after 90 min; and
- c) 85 % of the total amount of mesalazine in the standard formulation is released after 240 min;
as when measured in a model system using a USP Paddle System 2 operated at 37°C with stirring at 100 rpm.

7. (Currently Amended) The pharmaceutical Pharmaceutical formulation according to claim 1, further comprising a pharmaceutically acceptable binder, ~~preferably Povidone~~, in an amount less than or equal to an amount selected among from the group consisting of 1; 2; 3; 4; 5; 6; 7; 8; 9; 10 and 12 % by weight.

8. (Currently Amended) The pharmaceutical Pharmaceutical formulation according to claim 1, further comprising a coating, ~~preferably comprising or consisting of ethylcellulose.~~

9. (Currently Amended) The pharmaceutical Pharmaceutical formulation according to claim 1, further comprising a coating, wherein the ratio of the weight of said coating to the weight of said mesalazine or said pharmaceutically acceptable salt thereof being is selected among from the group consisting of 0.1-10%; 0.3-7%; 0.5-5%; 0.7-3%; 0.8-2%; and 0.9-1.5%.

10. (Currently Amended) The pharmaceutical Pharmaceutical formulation according to claim 1, essentially consisting essentially of mesalazine, a pharmaceutically acceptable binder and a coating.

11. (Currently Amended) The pharmaceutical Pharmaceutical formulation according to claim 1, wherein said pharmaceutical formulation is packed in a sachet.

12. (Currently Amended) A method Method for manufacturing a an oral pharmaceutical formulation in the form of a granulate comprising more than 60% by weight of mesalazine or a pharmaceutically acceptable salt thereof according to claim 1, comprising the steps:

- a) mixing mesalazine or a pharmaceutically acceptable salt thereof with granulation liquid to form a mixture;
- b) obtaining granulate by granulating, compacting or extruding the mixture;
- c) drying the granulate;
- d) optionally, adjusting the size of the granulate as necessary; and
- e) optionally, sieving the granulate as necessary;

characterised in the additional step of:

- f) coating the granulate to form coated granulate; and

optionally further:

- g) sieving the coated granulate; and
- h) air purging the coated granulate.

13. (Currently Amended) The method Method according to claim 12, wherein said coated granulate are packed in a sachet.

14. (Currently Amended) The method Method according to claim 12, wherein said granulation liquid consists of Povidone dissolved in water.

15. (Currently Amended) The method Method according to claim 12, wherein said drying step c) is performed in a fluid bed dryer

16. (Currently Amended) The method Method according to claim 12, wherein said adjusting of size step d) is performed by milling.

17. (Currently Amended) The method Method according to claim 12, wherein said sieving step e) is performed by selecting granulate passing a 1.8 mm sieve, but not passing a 0.5 mm sieve.

18. (Currently Amended) The method Method according to claim 12, wherein said coating step f) is performed with ethylcellulose.

19. (Currently Amended) The method Method according to claim 12, wherein said coating step f) is performed by applying an amount of coating material adjusted, according to the specific surface area, to be in the range 0.09 – 0.17 mg/cm², ~~preferably 0.11—0.15 mg/cm²~~, followed by drying.

20. (Currently Amended) The method Method according to claim 12, wherein said sieving step g) is performed on a rotation sieve, ~~preferably with a mesh size of 2.5 mm~~.

21. (Currently Amended) Use of mesalazine for the manufacture of a The pharmaceutical formulation according to claim 1, provided in a sachet comprising a total dosage amount of mesalazine or a pharmaceutically acceptable salt thereof chosen among selected from the group consisting of 0.5 g, 1.0 g, 1.5 g, 2 g, 3 g, 4 g, 5 g, 6 g, 8 g, and 10 g 0,5 g; 1,0 g; 1,5 g; 2 g; 3 g; 4 g; 5 g; 6 g; 8 g; and 10 g; preferably packed in a sachet.

22. (Currently Amended) Use according to claim 21, wherein the medicament is for the treatment of A method of treating intestinal bowel disease, preferably Crohn's Disease or Ulcerative Colitis comprising administering to a patient in need thereof an oral pharmaceutical formulation in the form of a granulate comprising more than 60% by weight of mesalazine or a pharmaceutically acceptable salt thereof.

23. (New) The method of claim 22, wherein said oral pharmaceutical formulation comprises an amount of mesalazine or pharmaceutically acceptable salt thereof selected from the group consisting of 0.5 g, 1.0 g, 1.5 g, 2 g, 3 g, 4 g, 5 g, 6 g, 8 g, and 10 g.

24. (New) The method of claim 22, comprising administering said oral pharmaceutical formulation at a dosing schedule selected from the group consisting of 1, 2, 3, and 4 times per day.

25. (New) The method of claim 22, wherein said intestinal bowel disease is selected from the group consisting of Crohn's Disease and Ulcerative Colitis.

26. (New) The pharmaceutical formulation according to claim 5, having in vitro release characteristics such that 40 – 60 % of the total amount of mesalazine or pharmaceutically acceptable salt thereof in the formulation is released after 90 min, when measured in a model system using a USP Paddle System 2 operated at 37°C with stirring at 100 rpm.

27. (New) The pharmaceutical formulation according to claim 6, having a similarity factor f_2 above 40 as compared to the standard formulation.

28. (New) The pharmaceutical formulation according to claim 6, having a similarity factor f_2 above 50 as compared to the standard formulation.

29. (New) The pharmaceutical formulation according to claim 7, wherein the pharmaceutically acceptable binder comprises Povidone.

30. (New) The pharmaceutical formulation according to claim 8, wherein the coating comprises ethylcellulose.

31. (New) The method according to claim 19, wherein said coating step f) is performed by applying an amount of coating material adjusted, according to the specific surface area, to be in the range 0.11 – 0.15 mg/cm².

32. (New) The method according to claim 20, wherein said sieving step g) is performed on a rotation sieve with a mesh size of 2.5 mm.